

Memorandum

540.0315

To : Mr. Jim Kuhl
Audit Support Unit Section (MIC:44)

Date January 20, 2006

From : John L. Waid
Senior Tax Counsel

Telephone: (916) 324-3828

Subject: SR -- XXX-XXXXXX
B—M--- P---, Inc.
Sales of Human Tissue for Research

I am responding to your memorandum dated June 7, 2005, to Acting Assistant Chief Counsel Selvi Stanislaus. You state that the taxpayer is engaged in drug manufacture and research and development and is currently being audited by the --- --- District. The taxpayer is requesting a refund of the use tax they reported on their purchases of human proteins and human enzymes used in their research and development activities. You attached to your memorandum a memorandum dated May 12, 2005, to Tax Policy Manager Jeff McGuire from Mark Noack, --- --- District Principal Auditor. Mr. Noack had four specific questions:

1. “Does the exemption for sales of human tissues extend to human proteins and enzymes?”
2. “Does the term ‘medical purposes’ include research and development activities for the purpose of discovering new drugs?”
3. “Are human proteins exempt regardless of the source? (i.e., blood, milk, sputum)?”
4. “If other animal proteins are combined with human proteins to form a solution, is the purchase of animal proteins exempt from sales or use tax?”

OPINIONA. General Discussion.

Revenue and Taxation Code section (Section) 33 reads as follows:

“Human whole blood, plasma, blood products, and blood derivatives, or any human body parts held in a bank for medical purposes, shall be exempt from taxation for any purpose.”

Section 33 appears in the general sections of the Revenue and Taxation Code prior to the start of the property tax sections (namely, Rev. & Tax. Code, § 50 et seq.). For the purpose of this discussion we will refer to human whole blood, plasma, blood products, and blood derivatives generally as “blood products” unless a specific reference is required.

The Legal Department has previously concluded that sales of blood products by blood banks, though sales of tangible personal property within the meaning of Section 6006, subdivision (a), are not subject to tax under Section 33. (Annot. 495.0045 (9/29/71).) We have also concluded that tax does not apply to the sale of human body parts for “medical usage.” (Annot. 540.0310 (1/21/77).) In addition, we have concluded that sales tax does not apply to transfers of cadaveric tissues to surgeons for transplantation, finding that such transactions are not regarded for California sales and use tax purposes as sales of tangible personal property. (Annot. 540.0110 (4/3/96).) Finally, Annotation 395.0673.250 (8/29/96) concluded that sales of blood constituted sales of property of a kind the sales of which could never be subject to sales tax, even at retail, citing Section 33.

On the other hand, we have also concluded that diagnostic substances (reagents) applied to a sample taken from the patient’s body to assist in diagnosing disease are not applied internally or externally to the body of the patient. For that reason, they do not come within the definition of medicines contained in Section 6369, subdivision (b), and their sales are subject to tax. (Annot. 425.0773 (1/11/93).) Moreover, we have concluded that the processing and mounting of a specimen of human tissue on a diagnostic slide does not result in the creation of tangible personal property when performed as an integral step in the process of diagnosis of human illness. The production and sale of a completed microscopic slide to be used for educational purposes, however, is a taxable sale of tangible personal property, even though a specimen of human tissue is made a part of the slide. (Annot. 515.1280 (8/30/71).)

B. Tax Consequences.

1. “Does the exemption for sales of human tissues extend to human proteins and enzymes?”

Section 33 provides an exemption for blood products and human body parts “held in a bank for medical purposes” (Emphasis added.) Before we discuss whether or not the human proteins and enzymes constitute “human body parts” under Section 33, we must determine if the

supplier is a “bank” within the meaning of the section. A review of our previous correspondence on this issue shows that this correspondence has either been with blood banks or has assumed that the purchaser was buying the products from a bank. As a result, we have not yet analyzed what requirements must be met for an entity to qualify as a “bank.”

“In interpreting particular words, phrases or clauses in a statute, it is a cardinal rule that the entire substance of the statute or that portion relating to the subject under review should be examined in order to determine the scope and purpose of the provision containing such words, phrases, or clauses. (*Wallace v. Payne* (1925) 197 Cal. 539, 544 [241 P. 879].)” (*West Pico Furniture Co. v. Pacific Finance Loans* (1970) 2 Cal.3d 594, 608.) The phrase “held in a bank” must therefore have some meaning. The legislative history of the statute refers to encouraging the stockpiling of supplies of blood and blood derivatives in blood banks. We thus conclude that the words “held in bank” were intended as words of limitation. Any available exemption applies only to the transfer of blood products or human body parts held by a “bank.” If the transferor does not qualify as a “bank” for the purposes of Section 33, no exemption is available.

Neither Section 33 nor any other section of the Revenue and Taxation Code defines the term “bank,” so we will have to look outside the Sales and Use Tax Law for a definition. (*King v. St. Bd. of Equal.* (1972) 22 Cal.App.3d 1006, 1010.) Health and Safety Code section 1600.2 defines a “blood bank” as “any place where human whole blood, and human whole blood derivatives specified by regulation, are collected, prepared, tested, processed, or stored, or from which human whole blood or human whole blood derivatives specified by regulation are distributed.” Health Services Department Regulation 997, interpreting and implementing this statute, provides, in part, that a “blood bank” is “a medical facility designed, equipped, and staffed to procure, to process, to store, or to distribute human whole blood or blood derivatives for transfusion purposes.” (Cal. Code Regs., tit. 17, § 997, subd. (a).) Health and Safety Code section 1635, subdivision (d), defines a “tissue bank” as “any place, establishment, or institution that collects, processes, stores, or distributes tissue for transplantation into human beings.”¹ Welfare and Institutions Code section 14132.34, subdivision (b), defines a “mothers’ milk bank” as “any person, firm, or corporation which engages in the not-for-profit procurement, processing, storage, distribution, or use of human milk, contributed by volunteer donors, in compliance with standards prescribed by the Human Milk Banking Association of North America.”²

The various types of banks defined by the statutes and regulations have certain characteristics in common: processing, storage, and distribution of the items entrusted to them. “Distribution” connotes a giving out of items (perhaps with reimbursement for costs) and not a sale for a consideration under Section 6006.³ (See Black’s Law Dict. (8th ed. 1999) p. 509, col. 2.) Thus, we conclude that a “bank,” for the purposes of Section 33, is an organization that processes,

¹ A “tissue bank” includes a sperm bank. (*Johnson v. Superior Court* (2002) 101 Cal.App.4th 869, 879.)

² A reference to a “nonprofit blood bank, artery bank, [or] eye bank” was deleted from Health and Safety Code section 7100 in 1968. (Stats. 1968, ch. 926.) These entities now appear to be covered under the general term “tissue bank.” (Health & Saf. Code, § 1635, subd. (c).)

³ Former Health and Safety Code section 7100, as noted above, required that eye, artery, and blood banks be nonprofit organizations. The current definitions cited above, do not appear to require that such organizations be not-for-profit entities, just that they not be selling the blood, tissue, or mothers’ milk.

stores, and distributes in a not-for-profit transaction blood products or human body parts pursuant to statute.⁴ Organizations that prepare property derived from human bodies for commercial sale do not qualify as “banks” within the meaning of Section 33.

In addition, and possibly more importantly, in order to operate within the State of California, each type of bank must be licensed by the Department of Health Services. (See Health & Saf. Code, §§ 1602.5 (blood banks); 1635.1 (tissue banks); & 1639.5, subd. (b) (mothers’ milk banks).) Failure to comply with its respective licensing requirements will potentially expose the offending organization to loss of its license and criminal prosecution. (Health & Saf. Code, §§ 1618 & 1620 (blood banks); and 1641 & 1643 (tissue banks, including mothers’ milk banks).) The reference to “banks” in Section 33 cannot be presumed to have been to organizations operating outside the law. That would create an absurd result. (See, e.g., *People v. Cregler* (1961) 56 Cal.2d 308, 312.) Therefore, we further conclude that a “bank,” within the meaning of Section 33, is an organization that not only performs only the tasks specified in its authorizing statutes but also possesses a valid license as required by applicable law. Sales of blood products and human body parts by entities that do not qualify as “banks” under Section 33 are thus subject to tax.

Now we turn to the second issue: do human proteins and enzymes qualify as “human body parts” within the meaning of Section 33? Section 33 specifies that its provisions apply to blood derivatives, but human body part derivatives, such as proteins and enzymes, are not mentioned.

Section 33 does not define the term “human body parts.” The Uniform Anatomical Gift Act defines “part,” however, as “an organ, tissue,⁵ eye, bone, artery, blood, fluid, or other portion of a human body or a pacemaker.” (Health & Saf. Code, § 7150.1, subd. (g).) Regarding the disposal of dead bodies, Health and Safety Code section 7054.4 provides that “recognizable anatomical parts, human tissues, anatomical human remains, or infectious waste following conclusion of scientific use shall be disposed of” in the required manner. The Legislature thus appears to use the term “human body parts” in its ordinary way – an item recognizable to the unaided eye as a part of the human body.⁶ Thus, we conclude that human body part derivatives, such as enzymes and proteins, are not the kinds of items the Legislature considered when it incorporated “human body parts” into the exemption provided by Section 33.⁷

In sum, if the entity supplying the property derived from human bodies does not have a valid license to operate as a “bank” as required by the Health and Safety Code, its transfers of tangible personal property are not exempt from tax under Section 33 no matter what the property is. In

⁴ Note that tissue banks are permitted to process, store, or distribute human tissue specifically for transplantation into human beings and for no other purpose. (See Health & Saf. Code, § 1635, subd. (d).)

⁵ It appears that proteins and enzymes would qualify as “tissues” for the purpose of regulation of tissue banks. Health and Safety Code section 1635, subdivision (c), defines “tissue” as “any human cell, group of cells, tissue or organ including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body.”

⁶ The separate reference in this last section to “recognizable anatomical parts” and “human tissues” is a strong indication that the Legislature views these two items as separate and distinct, so that a “tissue” is not a “human body part.” (See, *supra*, fn. 5.)

⁷ Such body part derivatives may qualify as “tissues” that may be held in a tissue bank. (See, *supra*, fns. 5 & 6.)

addition, we conclude that human enzymes and proteins are not “human body parts” within the meaning of Section 33. Their sale for research purposes would also not be exempt under Section 33, even when sold by an entity that qualifies as a “bank” within the meaning of that section.

2. “Does the term ‘medical purposes’ include research and development activities for the purpose of discovering new drugs?”

As noted above, we have previously concluded that “medical purposes” within the meaning of Section 33 include research and development undertaken to develop new drugs and medicines to treat human illness.

3. “Are human proteins exempt regardless of the source? (i.e. blood, milk, sputum)?”

See Response to Question No. 1 above.

4. “If other animal proteins are combined with human proteins to form a solution, is the purchase of animal proteins exempt from sales or use tax?”

There is no statutory exemption that covers the sale of animal proteins.⁸ The sale of the animal proteins is subject to tax.

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⁸ For example, Section 6358, subdivision (a), provides an exemption for sales of animals the products of which ordinarily constitute food for human consumption. That section does not, however, provide a general exemption for the sales of the products of such animals. (See, e.g., Annot 110.0060 (3/5/70).)